July 1, 2003

7-01-03

INSERTS TO THE TRANS FAT FINAL RULE

Other changes are noted in the document

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On September 18, 2001, the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, sent the Secretary of the Health and Human Services a letter requesting that the Secretary and FDA consider giving greater priority to the November 1999 proposal (Ref. 156) in light of the growing body of scientific evidence suggesting that consumption of *trans* fatty acids in foods increases the consumer's risk of developing CHD. The estimated public health benefits from increased consumer awareness of *trans* fat content in foods that were described in FDA's preliminary Regulatory Impact Analysis in the November 1999 proposal, and the subsequent evidence found in more recent studies, strongly supports the interests of the government to lower the incidence of and economic burden of CHD in the United States. This final rule summarizes the relevant comments that were received in response to the November 1999 proposal and provides the agency's conclusions regarding the labeling of *trans* fat on the Nutrition Facts panel.

FDA RES (the Secretary)

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FDA is issuing an ~~advance notice of proposed rulemaking~~ (ANPRM) elsewhere in this issue of the Federal Register that will solicit comment and additional consumer research that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in certain nutrient content claims and health claims, and to establish disclosure and disqualifying criteria for *trans* fat. In addition, the ANPRM is soliciting comment on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumer's understanding about cholesterol-raising lipids.

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Consumers would have information on the amount of *trans* fat in a product, along with other information about the amount of saturated fat and cholesterol. Consumers could use information about all three fats, not just saturated fat and cholesterol, to incorporate nutrition education information about recommended contributions for all three fats to the diet when making healthier food choices.

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That said, mandating the disclosure of this information does not require FDA to find that *trans* fatty acids actually cause CHD. In mandating the disclosure of this

information, FDA need not meet the standard of proof required to establish causation in a private tort action (*Glastetter v. Novartis Pharmaceutical Corp., 252* F.3d 986, 991 (8th Cir. 2001).

> **"The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50 percent) is required since the law believes it is unfair to require an individual to pay for another's tragedy unless it is shown that it is more likely than not that he caused it***."**

***In re "Agent Orange" Product Liability Litigation*, 597 F. Supp. 740, 781 (E.D.N.Y.) 1984), *aff'd* 818 F. 2d 145 (2d. Cir. 1987). In making its decision, the agency follows "the preventive perspective that [] agencies adopt in order to reduce public exposure to harmful substances." *Glastetter,* 252 F. 3d at 991, quoting *Hollander v. Sandoz Pharmaceuticals Corp.,* 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000). Accordingly, so long as we conclude that the consumer would reasonably expect this information to be disclosed and that it is scientifically justifiable to require its disclosure, we are justified in taking this action.**

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Accordingly, in the absence of a scientific basis or recommendation by an authoritative body, FDA is not establishing a DRV for *trans* fat. FDA intends to revisit this issue when there is more scientific information **that the agency can use to establish** an appropriate reference level for *trans* fat intake.

The agency recognizes that the absence of a DRV, and thus, the absence...

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Accordingly, as a result of concerns expressed in the comments, asserting that consumers may place undue emphasis on *trans* fat information relative to other heart-unhealthy fats from the presence of the *trans* fat proposed footnote, the agency is not proceeding at this time to incorporate a requirement for a footnote statement in this final rule. Instead, FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research on the use of a footnote and the language that may be used in a footnote to better reflect the dietary recommendations given in the above mentioned scientific reviews. **The ANPRM will also solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and to**

establish disclosure and disqualifying criteria for *trans* fat.

The agency is also requesting comments on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumer's understanding about cholesterol-raising lipids.

In light of the need for consumer research ~~on possible footnote statements~~ to evaluate consumers' understanding of the totality of dietary recommendations that address the selection of foods for a heart-healthy diet, the agency notes in the ANPRM that it intends to conduct such research and looks forward to receiving additional research from other interested parties.

In the meantime, as noted in the preceding comment, FDA is issuing this final rule to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. As noted above, most comments that opposed the proposed footnote stated a belief that even in the absence of a DV, consumers can still find quantitative information useful, and pointed to current labeling of mono- and polyunsaturated fats. In light of previous research that shows that consumers often use information on the Nutrition Facts panel to compare levels of nutrients in two or more foods, FDA concludes that it is important to proceed to list the quantitative information on *trans* fat at this time so that consumers will have information to use in comparing products and making dietary selections to reduce their intake of *trans* fat. The agency believes a footnote **or other labeling approach** about saturated fat, cholesterol, and *trans* fat, may provide additional assistance to convey the relative importance of each of these fats to consumers in a manner which enables them to understand their relative significance, to each other and in the context of a total daily diet. However, because of the public health impact of CHD in the United States and the additional time it will take to conduct the necessary consumer research, the agency concludes that it is essential to proceed at this time to mandate the listing of the quantitative information on *trans* fat so that consumers will be able to use that information to help maintain healthy dietary practices and to address an added footnote statement at a later time.

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In proposing nutrient content claims, the agency stated that "With the exception of the term "sugar free" and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs" (56 FR 60421 at 60429; November 27, 1991).] The approach of having an appropriate reference value for daily consumption provides a consistent and quantitative basis for defining claims. As stated in section V ~~above~~ of this document, **in the absence of the type of quantitative information from authoritative scientific groups on which the agency could support the establishment of a DRV for *trans* fat, the agency is providing for mandatory *trans* fat labeling, without a %DV.** Many comments supported this position. As a result of the absence of an appropriate reference value

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for *trans* fat, the agency has been hampered in developing an integrated approach that responds to the issues raised in the comments. Accordingly, the agency is withdrawing those sections of the November 1999 proposal pertaining to the establishment of a definition for "*trans* fat free," consideration of "reduced *trans* fat" and "reduced saturated and *trans* fat" claims and limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. FDA plans to continue to evaluate the evolving science and, when the science has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims, it will proceed to do so through a new rulemaking. **INSERT 123-1 goes here.**

As discussed under comment 17, FDA is issuing an ANPRM elsewhere in this issue of the Federal Register that will solicit comment and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and to establish disclosure and disqualifying criteria for *trans* fat.

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FDA will seek to ensure that it acts consistent with its obligations under the first amendment to allow truthful and non misleading speech.

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However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. **As described in the November 1999 proposal (64 FR 62746 at 62753), estimates of nutrient intakes based on food frequency data may be subject to systematic bias toward either over- or underestimation of intake, depending on the design of the food frequency questionnaire (Ref. 27). Available estimates of *trans* fat intake from food frequency questionnaires in observational studies are lower than estimates of *trans* fat intake from a national food consumption survey (Ref. 26), as summarized in the November 1999 proposal (64 FR 62746 at 62752 to 62753) and in Section IV of this document.** Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S. population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in Section IV, food intake is generally under-reported in consumption surveys **(Ref. 26).** Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake. **However, intake of *trans* fat from national consumption survey data is likely to underestimate actual intake to a lesser extent than does the lower reported intake of *trans* fat from food frequencies done in observation studies.** Additionally, intake of

trans fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

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The additional 0.0019 percent of energy represents 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation (1.964 percent - 0.0359 percent = 1.928 percent; 0.1 percent x 1.928 percent = 0.0019 percent).

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of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at $14.73 per hour) and delivery charges for one two-pound package delivered overnight (at $26.30). **The labor cost estimate was based on the average total compensation (wages and benefits) for handlers, equipment cleaners, helpers, and laborers in manufacturing industries. Overhead beyond benefits on the time to prepare a sample for testing is negligible.** The model reports a range of testing costs for *trans* fat given in table 4.

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In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of $30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. **Based on information in the model, three-quarters of the labels normally will be scheduled to be changed during the 30 month compliance period.** FDA estimates that **about 78,000 (25 percent) of the** almost **308,000** SKUs will **have to** be changed **earlier than would have been planned without this rule.** Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing

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and engraving, and the lost value of discarded labels. Across product categories, the average low relabeling cost per SKU is about **$1,100** and the average high relabeling cost per SKU is **$2,600**. The reported estimated costs

of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 5 shows **the total SKUs changed earlier than planned and** the total estimated costs of relabeling per product category and for the entire industry.

TABLE 5. RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	12,500	$10,941,000	$16,137,000	$27,231,000
Baking Ingredients	1,700	$1,615,000	$2,380,000	$3,899,000
Baby Foods	200	$164,000	$249,000	$404,000
Selected Beverages	9,000	$11,871,000	$16,659,000	$25,437,000
Breakfast Foods	1,000	$801,000	$1,237,000	$2,044,000
Selected Candy	4,100	$4,801,000	$6,974,000	$10,846,000
Selected Condiments, Dips and Spreads	3,700	$4,026,000	$5,970,000	$9,283,000
Dairy Foods	8,700	$10,744,000	$16,025,000	$25,032,000
Desserts	3,500	$2,762,000	$4,263,000	$7,042,000
Dietary Supplements	8,100	$13,449,000	$20,110,000	$34,041,000
Selected Dressings and Sauces	2,800	$2,908,000	$4,352,000	$6,757,000
Eggs	2,400	$1,983,000	$2,896,000	$5,086,000
Entrees	2,400	$2,012,000	$3,078,000	$5,032,000
Fats and Oils	800	$759,000	$1,160,000	$1,848,000
Fruits and Vegetables	7,500	$7,426,000	$10,915,000	$17,882,000
Seafood	1,400	$1,732,000	$2,541,000	$3,786,000
Side Dishes and Starches	4,100	$3,361,000	$5,124,000	$8,494,000
Snack Foods	3,600	$3,604,000	$5,288,000	$8,499,000
Soups	700	$809,000	$1,194,000	$1,854,000
Weight Control Foods	200	$196,000	$283,000	$489,000
Total	78,400	$85,964,000	$126,835,000	$204,986,000

4. Margarine Reformulation Costs

One consequence of this regulation will be the reformulation of some foods to reduce levels of *trans* fat. Because those changes in food composition are

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As mentioned previously, based on comments, FDA estimates that 15 percent of margarine products have already been reformulated to eliminate trans fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are

already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of trans fat. The different ingredients used in the products appear to have had no impact on the cost of production. As greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. **However, given that increases in costs of inputs, if any, have not been passed on with a change in 15 percent of margarine products, it seems quite reasonable that an additional smaller change (10 percent) will not result in significant increases in ingredient costs.**

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Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that the products that will be reformulated contain average amounts of *trans* fat, so the fraction of margarine products reformulated will equal the fraction of *trans* fat removed from margarine. The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule,

[start p. 166] FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only **300** margarine products. **The new data** will be used to **estimate that 30** margarine products that will reformulate as the result of this rule (10 percent of 300). Table 6 shows the cost of margarine reformulation.

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TABLE 6.–**COST OF** MARGARINE REFORMULATION

Cost of Reformulating per Product	**$440,000**
Products Reformulating	**30**
Total Cost	**$13,200,000**

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Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	$40,298,000	$44,930,000	$59,282,000

Relabeling	$85,964,000	$126,835,000	$204,986,000
Reformulation	$13,200,000	$13,200,000	$13,200,000
Total	$139,000,000	$185,000,000	$275,000,000

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because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA estimated: (1) The changes in *trans* fat intake that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided and dollar value of such benefits. **The rule may generate other benefits, but we do not quantify them. For example, consumers who are aware of the risks associated with *trans* fat will more readily find information on the *trans* fat content of various foods. The value of the reduction in search time for those consumers is an additional benefit of this final rule.**

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Insert for Page 170, preceding the paragraph before table 8:

As described in the November 1999 proposal (64 FR 62746 at 62768 and 62769), the regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) were based on 5 intervention studies that made, in total, 6 dietary comparisons between consumption of *trans* fat and cis-unsaturated fat (Refs. 7, 8, and 11 through 13). The regression equation for LDL-C showed that each additional percent of energy from *trans* fat was predicted to increase LDL-C by 1.5 mg/deciliter (dL) (0.040 millimol/liter) ($R^2 = 0.86$, $p = 0.0028$) when substituted for the same percent of energy from cis-monounsaturated fat, holding total energy intake constant. The regression equation for HDL-C showed that each additional percent of energy from *trans* fat was predicted to decrease HDL-C by 0.4 mg/dL (0.013 millimol/liter) ($R^2 = 0.88$, $p = 0.0019$), when substituted for the same percent of energy from cis-monounsaturated fat. The regression lines were forced through the origin because a zero change in intake will produce a zero change in lipoprotein concentrations (Refs. 62, 69, and 154). In carrying out the regression, differences between diets in fatty acids other

than *trans* fat and cis-monounsaturated fat were adjusted for by using regression coefficients from a previous meta-analysis of 27 intervention studies (Ref. 65).

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Revision for Page 170, rewording and expanding the last paragraph on P 170, the paragraph before table 8:

Sample calculations using Method 1 and Method 2 are summarized in Table 8 in this document. The table illustrates a decrease in *trans* fat intake of 0.1 percent of energy (calories) and shows the factors FDA used to relate a given decrease in *trans* fat intake to a corresponding change in CHD risk. **To estimate the change in CHD risk with change in *trans* fat intake, for each type of serum lipid, LDL-C and HDL-C, we multiplied the change in *trans* fat intake by three factors, representing 1) the change in serum lipid with change in *trans* fat intake, 2) the change in CHD risk with change in serum lipid, and 3) an adjustment for regression dilution. Table 8 shows that, for Method 1, based on changes in LDL-C, replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-monounsaturated fat would decrease CHD risk by 0.147 percent (-0.1 percent of energy from *trans* fat x 1.5 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.147 percent change in CHD risk). Based on changes in HDL-C, replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.140 percent (-0.1 percent of energy from *trans* fat x -0.4 mg HDL-C/dL per percent of energy from *trans* fat x -2.5 percent change in CHD risk per mg HDL-C/dL x 1.4 adjustment factor for regression dilution = -0.140 change in CHD risk based on changes in HDL-C). For Method 2, based on changes in both LDL-C and HDL-C, the decrease in CHD risk would be 0.287 percent (-0.147 percent based on LDL-C plus -0.140 percent based on HDL-C = -0.287 percent based on LDL-C + HDL-C).** FDA used these estimation methods to project the decrease in CHD risk in the November 1999 proposal (64 FR 62746 at 62767).

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Revision and expansion of Table 9 and accompanying revisions for text on Page 171, paragraph between Table 8 and Table 9.

The first four columns of data show the factors for substitution of *trans* fat for 100 percent of individual types of fatty acids or carbohydrate. We project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. By combining the factors in the first four data columns, we obtained the factors for substitution of *trans* fat for combinations of different fatty acids and carbohydrate, shown in the last three data columns.

We generated the factors in Table 9 by combining the results of two sets of

metaanalyses. Table 9 shows the result of linking 1) the regression equation coefficients of Katan et al (Ref. 62) and Zock et al (Ref. 69), for substitution of *trans* fat for cis-monounsaturated fat and 2) the regression equation coefficients of Mensink and Katan (Ref. 65), for substitution of saturated and cis-unsaturated fat for carbohydrate. The regression equations of Mensink and Katan (Ref. 65) were based on 27 intervention studies that made dietary comparisons for consumption of carbohydrate, saturated fat, cis-polyunsaturated fat and cis-monounsaturated fat. The regression equation for LDL-C included 57 dietary comparison data points from 24 studies, and showed that, holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase LDL-C by 1.28 mg/dL (0.033 millimol/liter) ($p < 0.001$), each additional percent of energy from cis-monounsaturated fat was predicted to lower LDL-C by 0.24 mg/dL (0.006 millimol/liter) ($p = 0.114$) and each additional percent of energy from cis-polyunsaturated fat was predicted to lower LDL-C by 0.55 mg/dL (0.014 millimol/liter) ($p = 0.002$). The regression equation for HDL-C included 59 dietary comparison data points from 25 studies, and showed that holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase HDL-C by 0.47 mg/dL (0.012 millimol/liter) ($p < 0.001$), each additional percent of energy from cis-monounsaturated fat was predicted to increase HDL-C by 0.34 mg/dL (0.009 millimol/liter) ($p < 0.001$) and each additional percent of energy from cis-polyunsaturated fat was predicted to increase HDL-C by 0.28 mg/dL (0.007 millimol/liter) ($p = 0.002$).

Comparison with the observed data showed that the predicted regression lines explained 64 percent of the variation in changes in LDL-C and 88 percent of the variation in changes in HDL-C. The coefficients of Mensink and Katan (Ref. 65) are expressed as substitution of each type of macronutrient for carbohydrate, but the coefficients of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) are expressed as substitution of *trans* fat for cis-monounsaturated fat. For comparability with the coefficients for *trans* fat, we expressed the coefficients of Mensink and Katan in terms of substitution of each type of macronutrient for cis-monounsaturated fat. As stated in the November 1999 proposal (64 FR 62746 at 62769), when substituted for one percent of energy from cis-monounsaturated fat, saturated fat raised LDL-C by 1.52 mg/dL, cis-polyunsaturated fat lowered LDL-C by 0.31 mg/dL, and carbohydrate raised LDL-C by 0.24 mg/dL. When substituted for one percent of energy from cis-monounsaturated fat, saturated fat raised HDL-C by 0.13 mg/dL, cis-polyunsaturated fat lowered HDL-C by 0.06 mg/dL, and carbohydrate lowered HDL-C by 0.34 mg/dL. We then combined these coefficients with the coefficients for *trans* fat, to obtain the changes in lipoprotein levels with *trans* fat substituted for different macronutrients, as shown in Table 9.

Table 9 also gives examples of changes in CHD risk with replacement of 0.1 percent of energy from *trans* fat by different macronutrients and combinations of macronutrients. Table 8 shows the general method and illustrates the calculation of estimated changes in CHD risk with replacement of *trans* fat by cis-monounsaturated fat. To account for each type of macronutrient substitution, we used the corresponding factors from Table 9 for

changes in serum lipids. For example, for cis-polyunsaturated fat, Table 9 gives the factor, 1.81 mg LDL-C/dL, for replacement of 1 percent of energy from cis-polyunsaturated fat by *trans* fat. For Method 1, based on changes in LDL-C, the replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-polyunsaturated fat would decrease CHD risk by 0.177 percent (-0.1 percent of energy from *trans* fat x 1.81 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.177 percent change in CHD risk). As noted above, we project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. The changes in CHD risk associated with specific combinations of fatty acids or carbohydrate are shown in the last three data columns. The first four data columns show the change in CHD risk associated with each individual type of fatty acid and carbohydrate. The column showing *trans* fat replaced by 100 percent saturated fat is included in Table 9 for completeness in illustrating the data and methods we used to estimate changes in CHD risk with different macronutrient substitutions. The inclusion of this column does not indicate that FDA projects that *trans* fat will be replaced by 100 percent saturated fat, or that FDA would encourage such an inappropriate substitution. Rather, the substitutions for *trans* fat that FDA considers most likely are shown later, in Table 10.

As mentioned earlier, and in the November 1999 proposal (64 FR 62746 at 62769), the economic analysis used changes in both LDL-C and HDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C. To allow readers to reproduce all of our estimated changes in CHD risk, Table 9 shows changes in CHD risk based on Method 2, LDL-C and HDL-C, as well as Method 1, LDL-C. In addition, the cells that show a decrease in CHD due to a 100 percent replacement of *trans* fat for saturated fat represent the relationship between HDL-C and CHD, a relationship that is more uncertain than the causal relationship between LDL-C and CHD. FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771-62773).

INSERT: p. 172-1 (table 9)

Table 9. Summary of changes in serum lipids and CHD risk with different macronutrient substitutions

A. Change in serum lipids with substitution of *trans* fatty acids for different types of fatty acids or carbohydrate

Macronutrient	*cis*-Monounsaturated fatty acid	*cis*-Polyunsaturated fatty acid	Saturated fatty acid	Carbohydrate	Half *cis*-monounsaturated and half *cis*-polyunsaturated	Half *cis*-monounsaturated and half saturated	Half *cis*-monounsaturated and half carbohydrate
Change in serum lipid when replaced by *trans* fat	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0.34	-0.53	-0.06	-0.37	-0.47	-0.23

B. Change in CHD risk with replacement of *trans* fatty acids by different types of fatty acids or carbohydrate

Macronutrient	*cis*-Monounsaturated fatty acid	*cis*-Polyunsaturated fatty acid	Saturated fatty acid	Carbohydrate	Half *cis*-monounsaturated and half cis-polyunsaturated	Half *cis*-monounsaturated and half saturated	Half *cis*-monounsaturated and half carbohydrate
Change in CHD risk with replacement of *trans* fat	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy
Method 1, LDL	-0.147	-0.177	0.002	-0.123	-0.162	-0.073	-0.135
HDL	-0.140	-0.119	-0.186	-0.021	-0.130	-0.163	-0.081
Method 2, LDL + HDL	-0.287	-0.296	-0.184	-0.144	-0.292	-0.235	-0.216

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A meta-analysis of the relative risk of CHD associated with *trans* fat intake was recently published (Ref. 102). The meta-analysis used the results of prospective observational studies in four cohorts: women in the U.S., men in the U.S., men in Finland, and men in the Netherlands. The results showed a pooled variance-weighted relative risk of 1.25 (95 percent confidence interval 1.11 to 1.40) for CHD associated with 2 percent of energy intake from *trans* fat. For 0.1 percent of energy intake from *trans* fat, the meta-analysis results would predict a relative risk of 1.0112 (confidence interval 1.0052 to 1.0170). That is, for 0.1 percent of energy intake from *trans* fat, the increase in CHD risk would be 1.12 percent (confidence interval 0.52 to 1.70 percent). In comparison, the largest change in CHD risk shown in Table 9, associated with 0.1 percent of energy intake from *trans* fat, is 0.162 percent using Method 1 and 0.292 percent using Method 2. Thus, the increase in CHD risk for 0.1 percent of energy intake from *trans* fat based on a meta-analysis of prospective studies is larger than the associated CHD risk estimated using either Method 1, LDL-C or Method 2, LDL-C and HDL-C. (The calculation of relative risk at different levels of *trans* fat intake is based on taking the natural logarithm. For 2 percent of energy intake from *trans* fat, the estimated relative risk was 1.25. The coefficient in the logistic regression is the natural logarithm of 1.25 = 0.223; 0.223/2 = 0.1116, the coefficient for 1 percent of energy from *trans* fat; 0.1116 x 0.1 = 0.0112, the coefficient for 0.1 percent of energy from *trans* fat; the antilogarithm of 0.0112 = 1.0112, the relative risk associated with 0.1 percent of energy from *trans* fat.)

Thus, FDA disagrees with the comment about relative risk in the prospective studies, and maintains that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL-C and HDL-C, by which *trans* fat contributes to CHD risk....

INSERT: p.191-1 (includes text taken from 192 and 193)

As shown in Table 2, a 0.0378 percent of energy decrease in *trans* fat intake is expected to occur by the effective date of the rule. Approximately three years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows the decreases in CHD risk that would be expected, three years after the effective date, for different examples of macronutrient substitutions for *trans* fat. The three specific substitutions shown in Table 10 are those that FDA used to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent cis-monounsaturated fat, (2) a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat, or (3) a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat (Ref. 73). Table 10 shows that, using one of these three substitutions, the predicted decrease in CHD risk would range from 0.027% to 0.061% for Method 1 and from 0.090% to 0.110% for Method 2.

(Move from pages 192 and 193 and footnote on page 193):

FDA has identified these likely substitutions, but recognizes that once reformulation begins, different combinations of ingredients may emerge. In order to estimate the health effects of reformulation, however, it is less important to identify the exact formulas to be used than it is to identify the range of possible changes in CHD risk. To estimate the potential health benefits from the reformulation of margarine FDA used **a probabilistic model with a** distribution of effects based on the distribution of possible changes in CHD risk associated with the three ingredient substitutions. FDA used a distribution rather than a weighted average because we did not know which combination was most likely, or what distribution of combinations would emerge. (The formal distribution we used was a BetaPERT, which uses three points: a minimum, an intermediate, and a maximum. The model used the change in CHD risk for a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent cis-monounsaturated fat as intermediate, and the change for a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.)

As shown in Table 10, the probabilistic model of substitutions for *trans* fat predicted a decrease in CHD risk of 0.052 percent using Method 1 and 0.106 percent using Method 2.

(Table 10)

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Revision for page 195 at the end of section a.:

For nonfatal cases, FDA estimated the cost to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have underestimated the health benefits from preventing nonfatal cases.

The medical costs for nonfatal CHD are also important. The American Heart Association estimates that the cost of a new event is about $22,700 and the total annual costs are $51.1 billion (Ref. 75). If 1.1 million cases lead to $22,700 per case, then all theses cases cost about $25 billion. The remaining 13.9 million cases average about $1,900 per year (($51.1 billion - $25 billion) /13.9 million). FDA, therefore, estimated medical costs per case as $22,700 in the first year and about $1,900 per year thereafter.

The total cost per nonfatal case is the sum of lost quality- adjusted life years multiplied by $100,000 per life year plus the medical costs of $22,700 plus $1,900 per year times the discounted life years. FDA estimated the morbidity cost per case to be about $282,000 ((0.29 x $100,000 x 8.4) + ($1,900 x 8.4) + $22,700).

[page 195] b. *Value of CHD morbidity and mortality prevented.* **In a May 30, 2003 Memorandum to the President's Management Council, OIRA Administrator John D. Graham recommended that agencies, when performing benefit cost-analysis, present results using both VSL and VSLY methods. Below we present estimates using both methods. The memorandum also recommends that agencies present analyses with larger VSLY estimates for senior citizens. Since many of the beneficiaries of this final rule are senior vitizens, larger VSLY values than the ones we have used will increase benefits further.**

FDA therefore estimates the benefits of this rule using two approaches that reflect different methods used in the economics literature. First, it calculates benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the number of nonfatal cases prevented multiplied by the costs of nonfatal cases, plus the savings in medical costs associated with reductions in nonfatal CHD. Its second calculation is like the first, except that it values reductions in mortality risk as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death (rather than the extensions to longevity multiplied by the value of increases in life-years gained), and calculates the value of reducing the number of nonfatal cases as simply the savings in medical costs. This section presents these two approaches in turn, beginning with the costs of nonfatal cases and medical costs.

Under the first approach, FDA estimated the costs of nonfatal cases to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years (discounted at 7 percent), or 10.6 discounted years discounted at 3 percent. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have underestimated the health benefits from preventing nonfatal cases.

There are also medical costs for nonfatal cases of CHD. The American Heart Association estimates that the cost of a new CHD case is about $22,700 and the total annual costs are $51.1 billion (Ref. 75). If 1.1 million cases lead to $22,700 per case, then all these cases cost about $25 billion. The remaining 13.9 million cases average about $1,900 per year (($51.1 billion - $25 billion) /13.9 million). FDA, therefore, estimated medical costs per case as $22,700 in the first year and about $1,900 per year thereafter.

Under the first approach, the total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by a value per life year plus the medical costs of $22,700 plus $1,900 per year times the discounted life years. FDA estimates the morbidity cost per case to be about $282,000 ((0.29 x $100,000 x 8.4) + ($1,900 x 8.4) + $22,700), assuming a value of $100,000 per quality adjusted life-year (VSLY).

In the first approach, FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound FDA uses $100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 77) use a similar estimate, and Garber and Phelps (Ref. 157) conclude that estimates of the value of a life

year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that $100,000 per life year is a reasonable estimate, given that median family income in 2002 was about $51,000. (Ref. 158) Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations implementing the 1990 amendments. FDA received no public comments on that estimate. To reflect other underlying literature, and following suggestions from other federal agencies, we begin with an estimate of the value of a statistical life (VSL) of $6.5 million. This estimate is consistent with the survey by Aldy and Viscusi (Ref. 159) on the premium for risk observed in labor markets. Annuitizing this value over 35 years at 3 percent and at 7 percent discount rates, as is consistent with OMB guidance, implies estimates of a value of an additional year of life of about $300,000 and $500,000. Therefore, Table 11a shows estimated benefits for three estimates of VSLYs: $100,000, $300,000 and $500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs.

TABLE 11a.— ANNUAL BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	Discount Rate	Number of Discounted Life-Years Gained		Mortality Related Benefits Estimated In year 3 After the Effective Date and Annually Thereafter (In Millions)		Total Benefits in Millions	
		Method 1	Method 2	Method 1	Method 2	Method 1	Method 2
$100,000	7 percent	1920	3840	$192	$384	$234	$477
$300,000	3 percent	2640	5280	$576	$1152	$968	$1973
$500,000	7 percent	1920	3840	$960	$1920	$1127	$2295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of $5 million and $6.5 million. This range of VSL estimates is consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks. (Ref. 159 and Ref. 160) FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Aldy and Viscusi are relatively low. Table 11b shows the annual benefits estimated in this way for the two different VSLs using both a 3 and 7 percent discount rate. The totals in the final 2 columns of the table are discounted, so direct multiplication of the previous columns does not give the totals in the final columns.

TABLE 11b.— ANNUAL BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE AND DISCOUNT RATES

VSL and discount rate	Expected Deaths Averted		Average Medical Costs per Nonfatal Case	Expected Nonfatal Cases Averted		Total Benefits Estimated in Year 3 After the Effective Date and Annually Thereafter (in Millions)	
	Method 1	Method 2		Method 1	Method 2	Method 1	Method 2
$5,000,000 (3%)	240	480	$43,000	360	720	$1,112	$2,225
$6,500,000 (3%)						$1,442	$2,884
$5,000,000 (7%)			$39,000			$991	$1,982
$6,500,000 (7%)						$1,285	$2,570

F. Overview of Benefits and Costs

To provide an overview of this analysis, we can compare the estimated total benefits and costs and summarize the sources of information used in making these estimates.

1. *Summary of Benefits and Costs*

Table 12 shows the timing of the discounted benefits and costs estimated for this rule, as well as the totals. **The benefits reported in Table 12 are based on a VSLY of $300,000 and a discount rate of 3%.** The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted [start page 196] at **3** percent), the medium cost estimate in **Table 12** comes to about $**12** million per year. With Method 1, the cost per life year saved would be **about $4,500** (**$12 million/2,600** life years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

	Effective date						
Years after publication	2	3	4	5	6	7	20
Costs							
Low	$139	none	none	none	none	none	$139
Medium	$185	none	none	none	none	none	$185
High	$275	none	none	none	none	none	$275

Benefits									
Method 1	Annual	none	none	none	$968	$940	$913	...	$603
	Cumulative total				$968	$1,908	$2,821	...	$13,130
Method 2	Annual	none	none	none	$1,973	$1,916	$1,860	...	$1,230
	Cumulative total				$1,973	$3,889	$5,748	...	$26,757

2. Summary of Information Sources

Table 12A summarizes the inputs, data sources and assumptions used in the Final Regulatory Impact Analysis for this final rule.

Table 12A. Summary of Inputs, Data Sources and Assumptions

Name of input	Value or distribution used	Type of estimate	Source of data or assumption
Current trans fat intake	Total intake, 2.55 percent of energy; intake from hydrogenated fat, 2.03 percent of energy (Table 1)	FDA's best estimate from available data.	USDA trans fat food composition database, (Ref. 40); USDA food group data from CSFII 1994-96, (Ref. 115).
Adjustment of trans fat intake for current level of margarine reformulation	0.063 percent of energy, decrease in current amount of trans fat intake from margarine (Table 2)	FDA's best estimate from available data.	15 percent decrease in current amount of trans fat intake from margarine based on industry comments on proposed rule.
Change in trans fat intake due to margarine reformulation	0.0359 percent of energy decrease (Table 2)	Low assumption based on uncertainty.	Assume 10 percent decrease in remaining trans fat from margarine.
Change in trans fat intake due to consumer choice	0.0019 percent of energy decrease (Table 2)	Low assumption based on uncertainty.	Assume 0.1 percent decrease in remaining trans fat intake from hydrogenated fat after margarine reformulation.
Overall change in trans fat intake due to labeling	0.0378 percent of energy decrease (Table 2 and 10)	Low assumption based on uncertainty. Excludes possible reformulation of products other than margarine.	Sum of two previous values.
Number of products to be	154,000 (Table 3)	High estimate based on uncertainty.	Main data sources: RTI labeling cost model (Ref. 129) for number of

Changes in CHD risk with changes in LDL-C	0.7% increase per 1 mg/dL increase in LDL-C (Table 8)	Data.	Published meta-analyses, Refs. 59, 60 and 61.
Changes in CHD risk with changes in HDL-C	2.5% increase per 1 mg/dL decrease in HDL-C (Table 8)	Data.	Published meta-analyses, Refs. 59, 60 and 61.
Adjustment for regression dilution	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (Table 8)	Data.	Published data, Ref. 64.
Overall change in CHD risk due to labeling	-0.052 percent, Method 1;-0.106 percent, Method 2 (Table 10)	Factors above combined with probabilistic model to account for macronutrient substitutions.	BetaPERT distribution, using the change in CHD risk for a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent cis-monounsaturated fat as intermediate, and the change for a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.
Time lag between effective date of labeling and first health benefits	3 years (Table 10).	Data.	3 years for serum lipid changes from dietary change. Ref. 137.
Heart attacks per year	Mean 1.1 million cases, std. dev. 110,000 cases	Data for mean. Assumption for std. dev.	Published data, Ref. 134.
Percent of heart attacks per year that are fatal	40 percent	Data.	Published data, Ref. 134.
Life-years saved	13, or 8.4 years discounted to the present at 7 percent (Table 10)	FDA's best estimate from available data.	Published data, Refs. 75, 76, 134.
Life-years saved	13, or 10.6 years discounted to the present at 3 percent (Table 10)	FDA's best estimate from available data.	Published data, Refs. 75, 76, 134.
Medical Costs saved per non-fatal case	$39,000 at 7 percent discount rate; $43,000 at 3 percent discount rate (Table 11)	FDA's best estimate from data and life expectancy calculations	Published data, Ref. 134.
Value of Statistical	$100,000; $300,000;	Data and FDA's best	$100,000 from Refs. 77, 68;

tested		Includes many products that have already been tested.	products likely to be affected and our judgement about what categories of products are likely to be affected.
Per product cost of testing	$261 to $371 (Table 4)	Data.	RTI labeling cost model, Ref. 129.
Percent of SKU label changes that can be coordinated with scheduled labeling changes	84 percent of branded SKUs, 50 percent of private label SKUs	FDA interpolation of information on 24 and 36 month compliance period proportions.	RTI labeling cost model, Ref. 129.
Per product category cost of relabeling	Varies (Table 5)	Data.	RTI labeling cost model, Ref. 129.
Number of margarines reformulated	30 (Table 6)	Low assumption based on uncertainty.	Assume 10 percent of margarine products reformulate
Per product cost of reformulation	$440,000 (Table 6)	Data.	Industry supplied information (64 FR 62745 at 62782, November 17, 1999)
Overall change in CHD risk per change in trans fat intake	0.147 percent decrease in CHD risk per 0.1 percent of energy decrease in trans fat intake. Method 1 (Table 8)	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: -0.1 percent x 1.5 x 0.7 x 1.4 = -0.147 percent, decrease in CHD risk.
Overall change in CHD risk per change in trans fat intake	0.287 percent decrease in CHD risk per 0.1 percent of energy decrease in trans fat intake. Method 2 (Table 8)	Intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: -0.1 percent x -0.4 x -2.5 x 1.4 = -0.140 percent, decrease in CHD risk due to change in HDL-C. Add to result from Method 1: -0.147 percent + (-0.140 percent) = -0.287 percent, decrease in CHD risk, Method 2.
Change in LDL-C with change in trans fat intake	1.5 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (Table 8)	Data	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake	-0.4 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (Table 8)	Data	Published meta-analyses, Refs. 62 and 69.
Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat	Various coefficients shown in Table 9.	FDA's best estimate from available data.	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.

Life Year (VSLY)	**$500,000 (Table 11)**	**estimate from available data.**	**$300,000 from $6.5 million for value of statistical life discounting 35 remaining years at 3 percent; $500,000 from $6.5 million for value of statistical life discounting 35 remaining years at 7 percent (Ref. 159).**
Value of Statistical Life (VSL)	**$5 million; $6,5 million (Table 11)**	**Data**	**General VSL literature (Ref. 159).**

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[start page 200] proportion of SKUs from small businesses as a whole equaled the proportion in the EED (73 percent). Across product categories the average low relabeling cost per SKU is about **$1,100** and the average high relabeling cost per SKU is **$2,600**. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 15 shows the total estimated costs of relabeling per product category and for all small businesses affected.

TABLE 15.—RANGE OF RELABELING COSTS FOR SMALL BUSINESSES BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	9,100	$7,987,000	$11,780,000	$19,879,000
Baking Ingredients	1,200	$1,179,000	$1,737,000	$2,846,000
Baby Foods	100	$120,000	$182,000	$295,000
Selected Beverages	6,600	$8,666,000	$12,161,000	$18,569,000
Breakfast Foods	700	$585,000	$903,000	$1,492,000
Selected Candy	3,000	$3,505,000	$5,091,000	$7,918,000
Selected Condiments, Dips and Spreads	2,700	$2,939,000	$4,358,000	$6,777,000
Dairy Foods	6,400	$7,843,000	$11,698,000	$18,273,000
Desserts	2,600	$2,016,000	$3,112,000	$5,141,000
Dietary Supplements	5,900	$9,818,000	$14,680,000	$24,850,000
Selected Dressings and Sauces	2,000	$2,123,000	$3,177,000	$4,933,000
Eggs	1,800	$1,448,000	$2,114,000	$3,713,000
Entrees	1,800	$1,469,000	$2,247,000	$3,673,000
Fats and Oils	600	$554,000	$847,000	$1,349,000
Fruits and Vegetables	5,500	$5,421,000	$7,968,000	$13,054,000
Seafood	1,000	$1,264,000	$1,855,000	$2,764,000
Side Dishes and Starches	3,000	$2,454,000	$3,741,000	$6,201,000
Snack Foods	2,600	$2,631,000	$3,860,000	$6,204,000
Soups	500	$591,000	$872,000	$1,353,000
Weight Control Foods	100	$143,000	$207,000	$357,000
Total	57,200	$62,754,000	$92,590,000	$149,640,000

Table 16 of this document shows the total costs to small businesses of the final rule. The adjusted total costs of the final rule equal the unadjusted total minus 1.8 percent of the total cost of the rule to all businesses (see 58 FR 2927 at 2928, January 6, 1993). The average cost per small business is about **$12,000**.

[page 201]

TABLE 16.—TOTAL COSTS FOR SMALL BUSINESSES

Cost Category	Low	Medium	High
Testing	$34,713,000	$38,703,000	$49,343,000
Relabeling	$62,754,000	$92,590,000	$137,891,000
Total	$97,467,000	$131,293,000	$187,234,000
Adjustment for Exemption	- $1,754,000	-$ 2,363,000	-$3,370,000
Adjusted Total	$96,000,000	$129,000,000	$195,000,000

FDA has attempted to place the burden that these costs will place on small businesses in the context of the entire environment in which small businesses exist. Eastern Research Group under contract with FDA has developed a model for estimating the impact of regulatory costs on the survival of small businesses. (Reference: Eastern Research Group, "Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and Its Applications to Four FDA-Regulated Industries," 2002.) This model does not cover the entire range of products covered by this final rule, so it is not possible to estimate the burden of this rule. However, Table 16a gives a sense of the impact that this rule may have on three industry categories that have many small businesses. The model estimates the additional number of small businesses that will have negative cash flow as a result of the costs of complying with a regulation.

TABLE 16a.—ILLUSTRATIONS OF IMPACTS ON SMALL BUSINESSES

Product Category	NAICS Code	Total Number of Small Businesses	Average Number SKUs Changed Early per Firm	Range of Costs per Firm	Standard Number of Small Businesses Lost Regardless of Regulation	Additional Small Businesses Lost Due to Compliance Costs of This Rule
Nonchocolate Confectionery Products	311340	590	6	$8,700 - $18,100	30 - 80	0 - 30
Cheese	311513	520	6	$7,500 - $16,300	40 - 90	0 - 20
Commercial Bakery Products	311812	2,760	4	$4,200 - $9,800	560	10 - 60

C. Regulatory Options

The Regulatory Flexibility Act requires that FDA consider options for regulatory relief for small entities.

1. Exemption for Small Businesses

The exemption of small businesses from the provisions of the final rule would provide regulatory relief. Table 16 of this document shows that small businesses are expected to bear total costs of about **$130** million as a result

of the final rule, an average of **$12,000** per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of **$12,000** per small business.

FDA believes that this option would not be desirable. On the one hand, because so many of the businesses in the food processing industry are classified as small by the Small Business Administration, if small businesses are exempted, most of the potential benefits from the final rule would not be realized. On the other hand, exempt businesses may be forced by market pressures to adopt the final label in any case. In addition, under section 403(q)(5)(E) of the act and implementing regulations, very small producers (those with fewer than 100 full-time employees) that: (1) File a notice with the Office of Nutritional Products, Labeling, and Dietary Supplements; (2) make very low volume products (fewer than 100,000 units annually); and (3)

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rule does not affect nutrient content or health claims, no small businesses will have to change the principal display panels or marketing of their products, which could be very costly.

With small businesses producing 85 percent of the products and 73percent of the SKUs, extending the compliance period for small businesses to the uniform effective date after January 1, 2006, would leave most labels not listing *trans* fat for almost 5 years after publication. This could result in significant confusion for consumers looking for *trans* fat content on labels and would make the Nutrition Facts panel inconsistent across product categories. This inconsistency would be contrary to the intent of the 1990 amendments. It also would undermine the policy goal of providing consistent nutrition information to consumers. Also, extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

3. **Exemptions for Small Entities**

FDA has chosen not to exempt small entities because consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative

contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat, and thus, not contain a level of *trans* fat that would contribute to CHD risk, does not prevent the absence of that fact on the label to no longer be considered a ''material fact'' for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers ''to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet'' (section 2(b)(1)(A) of Public Law 101–535).

Further, section 403(q)(2)(A) provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and strong consensus among the scientific community for reducing *trans* fat intake.

Survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary adviceto limit its consumption, the Nutrition Facts panel is where label users will expect to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement themost recent dietary guidance, and are likely to be misled about a food's basic characteristics.

Consumers need the *trans* fat information on products in order to determine how each product fits into their individual health goal for reducing *trans* fat intake in the context of their total daily diet. Thus, the agency is requiring *trans* fat labeling, regardless of whether claims are made or the levels of other fats are declared, to prevent products from being misleading under sections 403(a)(1) and 201(n) of the act. Therefore, as described in section III of this document, in this rulemaking FDA is relying on its authority under those sections as well as its authority under section 403(q)(2)(A) of the act to require that information on *trans* fat be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. Not requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, would be inconsistent with statutory directives for nutrition labeling in section 403(q) of the act.

Furthermore, the benefits of covering products made by small businesses exceed the costs that would be saved by exempting them. The medium estimated cost of covering small businesses is a one time cost of $129 million dollars (table 16). If we assume no benefits

from small businesses reformulating, then the benefits associated only with changing labels on all food products is $48 million per year using Method 1 ($99 million using Method 2). If small businesses produce at least 22% of food consumed annually, then benefits of covering products made by small businesses will exceed the costs that would be saved by exempting them after 20 years discounted at 3%. Using Method 2 for calculating benefits, small businesses would only need to account for production of at least 11% of food consumed. Since the Small Business Administration definition of small business includes the vast majority of food firms, products and SKUs, even the 22% amount is quite plausible.

D. Recordkeeping and Reporting Requirements

The Regulatory Flexibility Act requires FDA to include a description of the recordkeeping and reporting required for compliance with this final rule. This final rule does not require the preparation of a report or a record.

E. Summary

FDA finds that under the Regulatory Flexibility Act (5 U.S.C. 605(b)) this final rule will have a significant economic impact on a substantial number of small entities. Approximately 10,300 small businesses could be affected by the rule. The total burden on small entities is estimated to be between **$96** and **$184** million, or about **$9,300** to **$17,900** per entity.

INSERT: p. 208

The regulations set forth in this final rule require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 17.—ESTIMATED REPORTING BURDEN [1]

21 CFR Section	Number of Respondents	Responses per Respondent	Total Number of Responses	Hours per Response	Total Hours	Operating Costs (in thousands)
101 9(c)(2)(ii)	10,490	**27**	**278,100**	2	**556,200**	**$155,200**
101 36 (b)(2)	910	32	29,500	2	59,000	**$16,500**
Totals					**615,200**	**$171,700**

[1]There are no capital costs and or maintenance costs associated with this collection of information

The impact of these requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise food and dietary supplement labels. FDA used data from the 1999 County Business Patterns to estimate the number of respondents. The total number of responses is equal to the total number of SKUs being changed (table 3 of this

document). Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 2 hours per SKU (hours per response) to comply with the nutrition labeling requirements in this final rule. **This 2 hour per SKU estimate is based on assumptions about the amount of time required per SKU to test a product for *trans* fat, to redesign the label as needed, and to order the change for the label. FDA received no comments objecting to this estimate.**

INSERT: p. 209 -210

XIV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Section 403A of the Act (21 U.S.C. 343-1) is an express preemption provision. That section provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce" certain food labeling requirements, unless an exemption is provided by the Secretary (and, by delegation, FDA). Relevant to this final rule, one such requirement that States and political subdivisions may not adopt is "any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * *" (Act § 403A(a)(4), 21 U.S.C. 343-1(a)(4)). Prior to the effective date of this rule, this provision operated to preempt States from imposing nutrition labeling requirements concerning *trans* fat because no such requirements had been imposed by FDA under section 403(q). Once this rule becomes effective, States will be preempted from imposing any nutritional labeling requirements for *trans* fat that are not identical to those required by this rule.

Section 403A(a)(4) (21 U.S.C. 343-1(a)(4)) displaces both state legislative requirements and state common-law duties. *Medtronic v. Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cippollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548-49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements that are not identical to the *trans* fat labeling required by this final rule, including state tort-law imposed requirements, this preemptive effect is consistent with what Congress set forth in section 403(A) of the Act.

Section 4(c) of the Executive Order further requires that any "regulatory preemption of State law shall be restricted to the minimum level necessary" to achieve the regulatory objective. The agency is exercising its discretion under section 403(q)(2)(A) of the Act, in a manner that is consistent with such section, to require that the amount of *trans* fat be listed in the label or labeling of food. This action is the minimum level necessary to achieve the agency regulatory objective. Further, section 4(e) of the Executive Order provides that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." FDA sought input from all stakeholders through publication of the proposed rule in the Federal Register. Eight comments from State and local governmental entities were received; all supported the proposal. In addition, one supportive comment was received from a municipal health agency in response to the reopening of the comment period relating to the proposed footnote.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive Order 13132.

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TABLE 11B.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE AND DISCOUNT RATES

VSL and Discount Rate	Expected Deaths Averted		Average Medical Costs per Nonfatal Case	Ecpected Nonfatal Cases Averted		Total Benefits Estimated In Year 3 After the Effective Date and Annually Thereafter (in millions)	
	Method 1	Method 2		Method 1	Method 2	Method 1	Method 2
$500,000 (3%)	240	480	$43,000	360	720	$1,112	$2,225
$6,500,000 (3%)			$43,000			$1,442	$2,884
$5,000,000 (7%)			$39,000			$991	$1,982
$6,500,000 (7%)			$39,000			$1,285	$2,570

Overview

F. ~~Summary~~ of Benefits and Costs

To provide an overview of this analysis, we can compare the estimated total benefits and costs and summarize the sources of information used in making these estimates.

1. Summary of Benefits and Costs

Table 12 shows the timing of the discounted benefits and costs estimated for this rule, as well as the totals. The benefits reported in table 12 are based on a VSLY of $300,000 and a discount rate of 3 percent. The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted [~~start page 196~~] at 3 percent), the medium cost estimate in table 12 comes to about $12 million per year. With Method 1, the cost per life year saved would be about ~~$6,000~~ 4,500 ($12 million/2,~~000~~ 6 life years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

Cumulative Total as of Year 20

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

	Years After Publication	Effective Date							Infinite Stream
		2	3	4	5	6	7		
Costs									
Low		$139	none	none	none	none	none	...	$139
Medium		$185	none	none	none	none	none	...	$185
High		$275	none	none	none	none	none	...	$275
Benefits									
Method 1	Annual	none	none	none	$968	$940	$913	...	~~$603~~ delete
	Cumulative				$968	$1,908	$2,821	...	$13,130
Method 2	Annual	none	none	none	$1,973	$1,916	$1,860	...	~~$1,230~~ delete
	Cumulative				$1,973	$3,889	$5,784	...	$26,757

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on information in the FDA Labeling Cost Model (Ref. 129), FDA estimates that about 154,000 ~~60,000~~ food products in categories that could possibly include *trans* fat will be tested for *trans* fat content as a result of this rulemaking.

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In the proposed rule, FDA used a per product cost of testing for *trans* fat of $200. Some comments stated that this estimate is too low. They stated that tests had to be calibrated for each type of food to demonstrate accuracy of the test in the food matrix. FDA notes that manufacturers of many different types of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at $14.73 per hour) and delivery charges for one two-pound package delivered overnight (at $26.30). The labor cost estimate was based on the average total compensation (wages and benefits) for handlers, equipment cleaners, helpers, and laborers in manufacturing industries. Overhead beyond benefits on the time to prepare a sample for testing is negligible. The model reports a range of testing costs for *trans* fat given in table 4.

TABLE 4.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS

	Low	Medium	High
Cost per Product	$261	$291	$371
Total Testing Cost	$15,660,000	$17,460,000	$22,260,000

One comment suggested that butter and other products with high butter fat contents, such as some ice cream, would contain a reportable amount of naturally occurring *trans* fat, and that therefore, FDA had underestimated the costs of testing these products. In this final analysis, FDA has included testing